

PATENT COOPERATION TREATY

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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY
EXAMINING AUTHORITY

(PCT Rule 66)

| | |
|--|---|
| Date of mailing (day/month/year) 23.05.2006 | |
| Applicant's or agent's file reference 445/04393 | REPLY DUE within 1 month(s) from the above date of mailing |
| International application No. PCT/IL2005/000303 | International filing date (day/month/year) 17.03.2005 |
| Priority date (day/month/year) 18.03.2004 | |
| International Patent Classification (IPC) or both national classification and IPC INV. A61F2/00 | |
| Applicant CONTIPI LTD. et al. | |

1. ☒ The written opinion established by the International Searching Authority:

☒ is ☐ is not
 considered to be a written opinion of the International Preliminary Examining Authority
2. This first report contains indications relating to the following items:

☒ Box No. I Basis of the opinion
☐ Box No. II Priority
☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒ Box No. IV Lack of unity of invention
☒ Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☒ Box No. VI Certain documents cited
☒ Box No. VII Certain defects in the international application
☒ Box No. VIII Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(e).
How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.
Also: For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis. For an informal communication with the examiner, see Rule 66.6. For an additional opportunity to submit amendments, see Rule 66.4.
 If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary report on patentability (Chapter II of the PCT) must be established according to Rule 69.2 is: 18.07.2006

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Docketed By IR

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| Name and mailing address of the international preliminary examining authority: <div style="margin-top: 10px;"> European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016 </div> | Authorized Officer Mary, C Telephone No. +31 70 340-4408 |
|---|--|

To: ME ☐ MK ☐

OK ☐ OK ☐

FENSTER & Co.

**WRITTEN OPINION OF THE INTERNATIONAL
PRELIMINARY EXAMINING AUTHORITY**

International application No.
PCT/IL2005/000303

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This opinion is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this opinion is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-18 as originally filed

Claims, Numbers

1-35 received on 26.01.2006 with letter of 26.01.2006

Drawings, Sheets

1/20-20/20 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

**WRITTEN OPINION OF THE INTERNATIONAL
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 9-35

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search opinion has been established for the said claims Nos. 9-35
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- the written form ☐ has not been furnished
☐ does not comply with the standard
- the computer readable form ☐ has not been furnished
☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See supplemental sheet for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees, the applicant has:
- ☐ restricted the claims.
☐ paid additional fees.
☐ paid additional fees under protest.
☒ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☐ all parts.
☒ the parts relating to claims Nos. . 1-8

**WRITTEN OPINION OF THE INTERNATIONAL
PRELIMINARY EXAMINING AUTHORITY**

International application No.
PCT/IL2005/000303

Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|---------|
| Novelty (N) | Yes: Claims | |
| | No: Claims | 1-3,6-8 |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 1-8 |
| Industrial applicability (IA) | Yes: Claims | 1-8 |
| | No: Claims | |

2. Citations and explanations:

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

and /or

2. Non-written disclosures (Rule 70.9)

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item I

The amendments filed with the letter dated 26 January 2006, concerning claim 1 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following: "for at least one of a bladder, a urethra, a uterus, a rectum or a pouch of Douglas".

Thus, this report has been established as if these amendments had not been made.

Re Item III.

Rule 39.1(iv) and Rule 67.1 (iv) PCT - Method for treatment of the human or animal body by therapy: Claims 30-35 disclose a method of treating pelvic organ prolapse which is a method of treatment by therapy.

Re Item IV.

The separate inventions are:

- Claims 1-8: an apparatus for treating pelvic organ prolapse comprising a main body and an applicator
- Claims 9-19: an apparatus for treating pelvic organ prolapse comprising a main body and an anchoring body
- Claims 20-29: an apparatus for treating pelvic organ prolapse comprising a thin body which is deformable at least three points thereon.

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

The document EP0933069 cited in our search report discloses an apparatus for treating pelvic organ prolapse comprising a main body and an applicator. Beyond this prior art, the special technical features (in the meaning of Rule 13.2 of the P.C.T) left in the independant claims of the application are:

- In independant claim 1 : none.
- In independant claim 9: an apparatus for treating pelvic organ prolapse comprising a main body and an anchoring body.
- In independant claim 20: an apparatus for treating pelvic organ prolapse comprising a thin body which is deformable at least three points thereon.

**WRITTEN OPINION OF THE INTERNATIONAL
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(SEPARATE SHEET)**

International application No.

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No same or correspondent special technical feature can be found between claim 1 and claims 9 and 20. There is therefore no technical relationship involving same or corresponding special technical features between claim 1 and claims 9 and 20.

In conclusion, the groups of claims are not linked by common or corresponding special technical features and define 3 different inventions not linked by a single general inventive concept.

The application, hence does not meet the requirements of unity of invention as defined in Rules 13.1 and 13.2 PCT.

Re Item V.

1 Reference is made to the following documents:

D1 : EP 0 933 069 A (TSCHANNEN, PETER) 4 August 1999 (1999-08-04)

D2: US 2002/120243 A1 (KRAEMER ROBERT ET AL) 29 August 2002 (2002-08-29)

D3: US5618256 (L. Reimer) 8 April 1997 (1997-04-08)

D4: US5224494 (G. E. Enhoming) 6 July 1993 (1993-07-06)

The documents D3 and D4 were not cited in the international search report. Copies of the documents are appended hereto.

2 INDEPENDENT CLAIM 1

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

As stated in the description of the present application (page 1, lines 15-16), pelvic organ prolapse might appear alone or in combination with urinary stress incontinence. Document D1 discloses a device to treat urinary incontinence by elevating the deformed bladder neck (which is a form of prolapse) so that the bladder closure muscle can again performs its normal function. Consequently, document D1 discloses (the references in parentheses applying to this document):

An apparatus for treating pelvic organ prolapse comprising a main body (1) adapted to provide pelvic organ support when inserted into a vagina and an applicator (11) enclosing the main body for inserting said main body into a vagina.

Documents D3 and D4 disclose as well the subject-matter of claim 1. Therefore, claim 1 is not new in the sense of Article 33(2) PCT.

3 DEPENDENT CLAIMS 2-8

Dependent claims 2-8 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

- Claims 2-3, 6-8: novelty, see D1.

- Claims 4-5: inventive step, see D2. Claims 4 and 5 disclose that the apparatus comprises a soft layer, which is adapted to enhance comfort or to prevent necrosis. Document D2 discloses also a soft layer (film of plastic, non woven material or wax) which is obviously enhancing comfort or preventing necrosis. See also the clarity objections concerning these 2 claims, following point 4.

Re Item VIII.

- 4 Claims 4 and 5 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The following functional statements do not enable the skilled person to determine which technical features are necessary to perform the stated functions: a soft external layer adapted to enhance comfort or to prevent necrosis.
- 5 Claim 8 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.
- 6 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

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International application No.

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